

REMARKS

Claim 1 and Claims 61-79 are pending in this Application.

Claim 1 and Claims 61-79 have been rejected.

Claims 2-60 have been cancelled.

No claims have been allowed.

Claims 1, 64, 69, and 76 have been amended.

New Claims 80-106 have been added.

Claim 1 and Claims 61-106 remain in this Application.

Reconsideration of the claims is respectfully requested.

Specification

The Applicant has amended the text of the specification to correct an erroneous reference to the patent application as a “continuation-in-part.” The reference should read “continuation.” The Applicant has also corrected a typographical error in a patent application serial number and made a minor correction to the text that is supported by Figure 10. No new matter has been added to the specification as a result of these amendments.

Drawings

On Page 2 of the July 17, 2003 Office Action, the Examiner objected to the drawings of the patent application under 37 C.F.R. § 1.83(a). The Applicant has amended Claim 64 and Claim 76

to replace the terms “semicircular” and “elliptical” with other terms. The Applicant respectfully submits that the rejections directed to the drawings have now been overcome.

Support for Claim Limitations

The Examiner stated that the Applicant has not pointed out the support in the original disclosure for each of the newly presented claims and claim limitations (July 17, 2003 Office Action, Page 2, Lines 1-2). In response, the Applicant hereby submits the following support in the original disclosure for Claim 1 and for Claims 61-79 :

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| Claim 1 | Page 14, Lines 11-21 |
| Claim 61 | Page 15, Line 5 to Page 16, Line 17 and Figs. 6-8 |
| Claim 62 | Page 15, Lines 6-9 and Page 15, Line 22 to Page 16, Line 17 and Figs. 6-8 |
| Claim 63 | Page 15, Line 19 to Page 16, Line 6 |
| Claim 64 | (a) Page 16, Lines 7-17
(b) Page 16, Line 18 to Page 17, Line 11
(c) Page 19, Line 2 to Page 20, Line 1 and Figs. 17-20 |
| Claim 65 | (a) Page 16, Lines 15-17 and Fig. 8
(b) Page 17, Lines 2-4 and Fig. 10
(c) Page 17, Line 22 to Page 18, Line 1 and Fig. 13
(d) Page 21, Line 12 to Page 22, Line 5 and Figs. 24-27 |
| Claim 66 | Page 16, Lines 7-17 |
| Claim 67 | Page 16, Lines 13-15 |

- Claim 68 Page 16, Lines 11-13
- Claim 69 Page 21, Lines 9-11
- Claim 70 Page 25, Line 11 to Page 26, Line 8
- Claim 71 Page 19, Lines 2-4 and Figs. 17-20
- Claim 72 (a) Page 19, Line 12 to Page 20, Line 1
(b) Page 26, Lines 8-13
- Claim 73 Page 26, Lines 8-13
- Claim 74 Page 15, Line 19 to Page 16, Line 17 and Figs. 6-8
- Claim 75 Page 16, Lines 13-15
- Claim 76 (a) Page 16, Lines 7-17
(b) Page 16, Line 18 to Page 17, Line 11
(c) Page 19, Line 2 to Page 20, Line 1 and Figs. 17-20
- Claim 77 (a) Page 16, Lines 15-17 and Fig. 8
(b) Page 17, Lines 2-4 and Fig. 10
(c) Page 17, Line 22 to Page 18, Line 1 and Fig. 13
(d) Page 21, Line 12 to Page 22, Line 5 and Figs. 24-27
- Claim 78 Page 16, Lines 7-17
- Claim 79 Page 16, Lines 13-15

35 U.S.C. § 102(b) Claim Rejections

On Pages 3-4 of the July 17, 2003 Office Action, the Examiner rejected Claims 61-68, 70, and 74-79 under 35 U.S.C. § 102(b) as being anticipated by United States Patent No. 5,354,331 to *Schachar*. The Applicant respectfully traverses these rejections.

Section 102, in pertinent part, provides that a “person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.” It is axiomatic that anticipation of a claim under §102 can be found only if the prior art reference discloses every element of the claim. *See, In re King*, 231 U.S.P.Q. 136, 138 (Fed. Cir. 1986) (citing with approval, *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984)).

Amended Claim 61 reads as follows:

61. (Previously presented) A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising:

an elongated body having a first end, a second end, a first surface and a second surface, said first surface and said second surface being adapted to contact said sclera, and means for expanding said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball. (Emphasis added).

A determination of anticipation, with respect to Claim 61, requires that each feature claimed therein be described in sufficient detail in the *Schachar* reference to enable one of ordinary skill in the art to make and practice the claimed invention.

The Examiner stated that “An elongated body and an expanding means as set forth in instant

claim 61 are evident from column 7, lines 1-12 and 36-42; column 5, lines 36-41; and the drawings [of the *Schachar* patent].” (July 17, 2003 Office Action, Page 3, Lines 2-4). The Applicant respectfully traverses this statement of the Examiner.

The *Schachar* patent is directed to a scleral expansion band in the shape of a ring. It is evident from the drawings of the *Schachar* patent and from the text at Column 7, Lines 1-12, that the *Schachar* patent is directed to a device that forms a “complete band.” (*Schachar*, Column 7, Line 3). The drawings and the text of *Schachar* make it clear that the “complete band” is a ring. The *Schachar* ring does not have a first end and a second end. The *Schachar* ring is not an “elongate body” as that term is used in the present patent application. Therefore the Applicant respectfully disagrees with the Examiner’s characterization of the *Schachar* reference.

The *Schachar* reference states: “The scleral expansion band may also be made in a plurality of parts that can be assembled prior to use or may be installed separately to form a complete band.” (*Schachar*, Column 7, Lines 1-3). It is clear that the “plurality of parts” are assembled to form a “complete band.” There is no teaching or suggestion of using the individual parts of the complete scleral expansion band separately (i.e., not formed into a complete ring). On the contrary, the individual parts of the scleral expansion band are always assembled into a complete band. The assembly of the parts may be “prior to use” (i.e., after the parts are assembled into a complete band, then the complete band is inserted into the sclera of the eye). Alternatively, the parts may be “installed separately” (i.e., connected to each other one at a time within the eye) “to form a complete band” within the sclera of the eye. In either case, the individual parts of the scleral expansion band

are never used separately. They are always used in a complete, unitary scleral expansion band has the form of a continuous ring.

The length of the *Schachar* ring may be adjusted by a “tangential screw mechanism” (*Schachar*, Column 7, Line 10). There is no disclosure, teaching or even a hint in the *Schachar* patent that the tangential screw mechanism is an expansion means. The only function of the tangential screw mechanism is to adjust the circumference of the band to adjust how much the complete band expands the sclera. (*Schachar*, Column 7, Lines 10-11). The tangential screw mechanism adjusts the circumference of the complete band before the complete band is inserted into the eye. The tangential screw mechanism is not inserted into the eye. Therefore the tangential screw mechanism is not an expansion means because it is not part of the scleral prosthesis. It is the complete band that expands the sclera. Therefore, the “expanding means” of Claim 62 may not be viewed as the ridge (or thread) of the screw mechanism described at Column 7, Lines 8-12 of the *Schachar* patent.

The Examiner also stated that “It has been held that an element that is “adapted to” perform a function is not a positive limitation but only requires the ability so to perform; it does not constitute a limitation in any patentable sense (*In re Hutchinson*, 69 USPQ 138 [CCPA 1946])” (July 17, 2003 Office Action, Page 3, Lines 4-6). The Applicant respectfully submits that the statement in the *Hutchinson* case that relates to the use of the phrase “adapted to” in an introductory clause is dictum. This is because Claim 42 in the *Hutchinson* case was anticipated by a prior art reference (Moxon) even if the introductory clause in Claim 42 had been construed as a patentable limitation

(69 USPQ 138, 141 (CCPA 1946). Therefore the dictum against using the phrase “adapted to” was not necessary to the holding of the case.

Therefore the Applicant respectfully submits that the phrase “adapted to” may be properly used in claim language when the meaning of the claim is clear. See, for example, the claims of United States Patent No. 5,358,451 to *Lacombe et al.*

The *Schachar* patent fails to disclose or even hint at the structure of the elongated body of the present invention. A ring-shaped “complete band” does not have a first end and a second end. These comments also apply to Claims 62-68, 70 and 74-79. The Applicant respectfully submits that the rejections under 35 U.S.C. § 102(b) have now been overcome.

35 U.S.C. § 103(a) Claim Rejections

On Pages 2-4 of the July 17, 2003 Office Action, the Examiner rejected Claims 69 and 71-73 under 35 U.S.C. § 103(a) as being obvious in view of United States Patent No. 5,354,331 to *Schachar*. The Applicant respectfully traverses these rejections.

During *ex parte* examinations of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness

is established does the burden shift to the applicant to produce evidence of non-obviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 USPQ 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not be based on an applicant's disclosure. MPEP § 2142.

The Applicant respectfully submits that the Patent Office has not established a *prima facie* case of obviousness with respect to Claim 69 and Claims 71-73 of the Applicant's invention. Claim 69 depends from Claim 66 which, in turn, depends from amended Claim 61. The Applicant directs the Examiner's attention to amended Claim 61 which shows novel and unique features:

61. (Previously presented) A prosthesis adapted for contact with the sclera of an eyeball, said prosthesis comprising:

an elongated body having a first end, a second end, a first surface and a second surface, said first surface and said second surface being adapted to contact said sclera, and means for expanding said contacted sclera to increase the effective working distance of the ciliary muscle of the eyeball. (Emphasis added).

For the reasons set forth above in connection with the rejections under § 102(b), the Applicant respectfully submits that the *Schachar* patent does not disclose, teach or even hint at the structure of the present invention. The Examiner stated that the dimensions recited in Claim 69 would have been obvious “from anatomical considerations” for the “plurality of parts” recited in Column 7, Line 2 of the *Schachar* patent. The Applicant respectfully traverses this assertion of the Examiner because the “plurality of parts” in *Schachar* form a “complete band” as previously described. There is no teaching, suggestion or hint in *Schachar* to use an individual part of the “plurality of parts” as a separate prosthesis. The *Schachar* patent teaches using the “plurality of parts” collectively as a “complete band.” Unlike the present invention, there is nothing in *Schachar* that suggests the dimensions of an individual separate prosthesis. The Applicant respectfully submits that the obviousness rejection of Claim 69 has been overcome.

With respect to Claims 71-73, the Examiner also stated that the use of an internal cavity filled with saline solution would have been obvious from the *Schachar* patent. The Examiner cited Column 6, Lines 40-45 and Column 6, Lines 45-64. The Applicant respectfully traverses these rejections. First, unlike the ring shaped “complete band” of the *Schachar* patent, the prosthesis of the present invention claimed in Claims 71-73 comprises an elongated body with a first free end and

a second free end. Second, there is nothing in the cited portion of the *Schachar* patent (or in any other portion of the *Schachar* patent) that discloses, suggests or even hints at the concept of having a prosthesis with an internal cavity filled with saline solution or the like. The “diversity of materials” cited in Column 6 of the *Schachar* patent do not include any liquids such as saline solution. The Applicant’s concept of using a prosthesis with an internal cavity filled with saline solution or the like is therefore not obvious in view of the *Schachar* patent. The Applicant respectfully submits that the obviousness rejections of Claims 71-73 have been overcome.

The Applicant has amended Claim 64 and Claim 76 to replace the word “semicircular” with the word “curved.” The Applicant respectfully submits that the specification and drawings support the use of the word “curved” to describe the prosthesis of the invention. The Applicant also submits that the word “curved” is broader than the word “semicircular.”

The Applicant has also amended Claim 64 and Claim 76 to replace the word “elliptical” with the word “elongated.” The Applicant respectfully submits that the specification and drawings support the use of the word “elongated” to describe the prosthesis of the invention.

The Applicant therefore respectfully requests that Claim 1 and Claims 61-79 be deemed to be allowable claims and that Claim 1 and Claims 61-79 be passed to allowance. The Applicant has added new Claims 80-106. For the reasons set forth above, the Applicant submits that the new Claims 80-106 are allowable claims. The Applicant therefore respectfully requests that Claims 80-106 also be passed to allowance.

The Applicant denies any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. The Applicant reserves the right to submit further arguments in support of its above-stated position, as well as the right to introduce relevant secondary considerations including long-felt but unresolved needs in the industry, failed attempts by others to invent the invention, and the like, should that become necessary.

SUMMARY

For the reasons given above, the Applicant respectfully requests reconsideration and allowance of pending claims and that this patent application be passed to issue. Any additional fees due by virtue of this Amendment should be charged to Deposit Account No. 50-0208. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting prosecution of this Application, the Applicant respectfully invites the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@davismunck.com.

Respectfully submitted,

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